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AB

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 10/753,882 | 01/09/2004 | Alon Shalev | SHALEV=2A | 6142 |
| 1444 | 7590 | 12/16/2005 | EXAMINER | |
| BROWDY AND NEIMARK, P.L.L.C. | | | GETZOW, SCOTT M | |
| 624 NINTH STREET, NW | | | | |
| SUITE 300 | | | ART UNIT | PAPER NUMBER |
| WASHINGTON, DC 20001-5303 | | | 3762 | |

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/753,882 | SHALEV ET AL. |
| | Examiner Scott M. Getzow | Art Unit 3762 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) See Continuation Sheet is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) See Continuation Sheet is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/25/05, 5/13/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3,9-12,17,26,29,31,37-41,45,46,54,57,58,67-76,79,80,131-140,143,144 and 407-415.

Continuation of Disposition of Claims: Claims rejected are 1,3,9-12,17,26,29,31,37-41,45,46,54,57,58,67-76,79,80,131-140,143,144 and 407-415.

Claim Objections

1. Claims 43,44 are objected to because of the following informalities: Claims 43 and 44 have not been formally cancelled. Appropriate correction is required.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1,3,9,10,11,12,17,26,29,31,37,38,39,40,41,45,46,54,57,58 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1,2,5-30,32,33,36-61,63-216 of copending Application No. 10/258714. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 67-76,79,80,131-140,143,144,407-415 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,5-30,32,33,36-61,63-216 of copending Application No. 10/258714 in view of Lerner (6410046). Lerner teaches modulation of drug delivery, which causes permeability of the BBB to be increased and allowing drugs to enter the CNS; see especially col. 8, lines 45 to col. 9, line 13, and col. 9, lines 60+ which teaches that ultrasound or electrical current can help facilitate drug delivery into the CNS. Col. 11, lines 55+ teach the various molecules that can be delivered.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1,3,9-12,17,26,58,67-76,79,80,407-409 are rejected under 35 U.S.C.

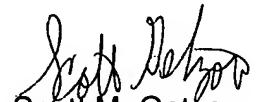
103(a) as being unpatentable over Lerner (6410046).

As mentioned above, Lerner teaches the application of electrical current and ultrasound energy to promote the ability of drugs to enter the CNS via the BBB. The control unit of claim 1 is considered to be obvious over the structure of Lerner in that such a control unit would be analogous to the structure that allows the current intensity to be varied, as taught in col. 8. Further, the location of the control unit is considered to be intended use, not a structural limitation. Also, one of ordinary skill in the art would understand that manipulation of the frequency and shape of the current waveform would be expected in order to maximize the effectiveness of the treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (571) 272-4946. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott M. Getzow
Primary Examiner
Art Unit 3762

SMG